Regulatory Analysis Form

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REVIEW COMMISSION

(1) Agency

Department of State, Bureau of Professional and Occupational Affairs, State Board of Veterinary Medicine

(2) I.D. Number (Governor's Office Use)

16A-5712

IRRC Number: 2276

(3) Short Title

Prescription Drugs

(4) PA Code Cite

49 Pa. Code, § 31.21
(Principle 8)

(5) Agency Contacts & Telephone Numbers

Primary Contact: Teresa Lazo-Miller, Counsel, State Board of Veterinary Medicine (717) 783-7200

Secondary Contact: Joyce McKeever, Deputy Chief Counsel, Department of State (717) 783-7200

(6) Type of Rulemaking (check one)

_X_ **Proposed Rulemaking**
___ **Final Order Adopting Regulation**
___ **Policy Statement**

(7) Is a 120-Day Emergency Certification Attached?

_X_ **No**
___ **Yes: By the Attorney General**
___ **Yes: By the Governor**

(8) Briefly explain the regulation in clear and nontechnical language.

The proposed regulation would: require veterinarians to dispense prescription drugs, other than for food animals, in child resistant or original packaging; require veterinarians to put pertinent information on prescription drug labels; and require veterinarians to dispense or administer only current, unexpired medications and provide that a veterinarian will not be disciplined for refusing to issue a written prescription under certain circumstances.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

Section 5(2) of the Veterinary Medical Practice Act (Act), Act of December 27, 1974, P.L. 995, No. 326 as amended, 63 P.S. §485.5(2) authorizes the Board to adopt regulations regarding professional conduct.

Regulatory Analysis Form

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No. However, federal law contains mandates for packaging and labeling prescription drugs intended for human consumption.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Many drugs dispensed for companion animals are stored in homes with children. The same safety concerns that prompted legislation requiring child resistant packaging for drugs intended for human consumption therefore apply to veterinary drugs that are dispensed for companion animals. In addition, many drugs dispensed for other types of animals may be stored in an area to which children have access. The public interest in requiring child resistant packaging would be addressed by the regulation. Labeling drugs ensures that the drug can be identified.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

Poisoning may result from the accidental ingestion of prescription drugs. This danger is increased if drugs are not packaged in child resistant packaging. The Board's proposed regulation would reduce the risk of accidental poisoning. In addition, the proposed regulation would facilitate treatment by requiring that drugs be labeled.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The general public will benefit from having veterinary drugs dispensed in child resistant packaging. In addition, the general public will benefit from the requirement that veterinarians administer and dispense only current, unexpired medications because these medications are effective in treating diseases of animals. Finally, the general public will benefit from the regulation that veterinarians exercise professional judgment in determining whether or not to provide a prescription to a client because veterinarians serving food-producing animals are better able to monitor the use of drugs in the animals and are, therefore, better able to protect the quality of the food supply.

Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

There are approximately 4,700 licensed veterinarians in Pennsylvania who might be adversely effected by the regulation. The adverse effect would be in the form of additional costs to package prescription drugs in child resistant packaging and in labeling prescription drugs. Many veterinarians already dispense prescription drugs in child resistant packaging. Veterinarians that dispense prescription drugs only in original packaging will not be affected by the proposed regulatory change and there is an exception for clients who may have difficulty opening child resistant packaging.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

All licensed veterinarians in the Commonwealth of Pennsylvania would be required to comply with the regulation. As stated above, there are approximately 4,700 licensed veterinarians in the Commonwealth of Pennsylvania.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

In developing and drafting the regulation, the Board solicited comment from the Pennsylvania Veterinary Medical Association, regional veterinary medical associations, associations of animal health technicians and schools of veterinary medicine.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

The Board projects that the regulated community will experience only minimal additional costs in procuring child resistant packaging over regular packaging and in meeting the requirement of labeling prescription drugs. In addition, many veterinarians in the Commonwealth already dispense prescription medications, particularly for companion animals, in safety closure packaging.

Regulatory Analysis Form

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

There are no specific costs or savings to local governments associated with the regulation.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

There are no specific costs or savings to the state government associated with implementation of the regulation.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY	FY +1	FY +2	FY +3	FY +4	FY +5
SAVINGS:						
Regulated Community	**0**	**0**	**0**	**0**	**0**	**0**
Local Government	**0**	**0**	**0**	**0**	**0**	**0**
State Government	**0**	**0**	**0**	**0**	**0**	**0**
Total Savings						
COSTS:						
Regulated Community	**minimal**	**minimal**	**minimal**	**minimal**	**minimal**	**minimal**
Local Government	**0**	**0**	**0**	**0**	**0**	**0**
State Government	**0**	**0**	**0**	**0**	**0**	**0**
Total Costs						
REVENUE LOSSES:						
Regulated Community	**0**	**0**	**0**	**0**	**0**	**0**
Local Government	**0**	**0**	**0**	**0**	**0**	**0**
State Government	**0**	**0**	**0**	**0**	**0**	**0**
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

Based on its own members' experience in purchasing child resistant packaging, the Board projects that there will be only a minimal additional cost to the regulated community to comply with the regulation.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

N/A	FY 96-97	FY 97-98	FY 98-99	FY 99-00
Program	**FY -3**	**FY -2**	**FY -1**	**Current FY**
Veterinary Board	**182,445.32**	**221,044.29**	**261,139.28**	**259,000.00**

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The benefits outweigh the minimal costs of the regulation in protecting the safety of the population, particularly that of children who are especially vulnerable to accidental poisoning.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Because Section 5(2) of the Act, 63 P.S. § 485.5(2) provides that the Board is to adopt rules of professional conduct by promulgating regulations, the Board considered no nonregulatory alternatives to achieve the goals.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

The Board considered numerous alternative regulatory schemes including requiring that all medications rather than just prescription drugs be placed in safety closure packaging, and requiring that veterinarians release a prescription to any client who requests one. The Board restricted its regulation to the packaging of prescription drugs, which is consistent with federal law. In addition, the Board determined that a veterinarian should be permitted to exercise professional judgment in determining whether or not to provide a client with a written prescription rather than a dispensed medication, based on numerous comments from farm and food animal practitioners warning of dangers to the food supply should the regulation require a veterinarian to provide a prescription.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

None of the provisions of the proposed regulation are more stringent than federal standards.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This regulation is similar to that in some of the states surrounding Pennsylvania and will not put Pennsylvania at a competitive disadvantage. Maryland requires that veterinarians dispense only unexpired medications. (Code of Maryland Regulations 15.14.01.12). West Virginia requires veterinarians to dispense repackaged drugs for companion animals in approved child resistant packaging, except upon the specific request of the client. (West Virginia Code of State Rules, W.Va. Code State R. tit. 26, §4-3.5(D). West Virginia also requires veterinarians to include information on the label of a dispensed drug, similar to the information required by the proposed regulation. (West Virginia Code of State Rules, W.Va. Code State R. tit. 26 §6-3.5(D)). New Jersey's Veterinary Board regulations also require specific information on the label of a dispensed veterinary drug. (New Jersey Administrative Code, N.J. Admin. Code tit. 13:44, §4.1(a)). Delaware and New York do not specifically address labeling, packaging, or dispensing requirements.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

This regulation will not effect any existing or proposed regulations of the Board.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Board holds public meetings on a monthly basis and public comment at the meetings is invited. The next meetings of the State Board of Veterinary Medicine are as follows: March 21, 2002, May 23, 2002, July 18, 2002, September 5, 2002, October 24, 2002, and December 12, 2002.

Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

The Board anticipates no reporting, record keeping or other paperwork requirements associated with this regulation.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The Board has identified no affected groups whose needs must be considered in this regulation.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The Board anticipates that the regulation will be effective upon final publication in the Pennsylvania Bulletin. Veterinarians will be expected to be in full compliance with the regulation within one month of its final publication date.

(31) Provide the schedule for continual review of the regulation.

The Board continuously reviews regulations at its monthly meetings.

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FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

2002 JUN 10 A 11:01

REVIEW COMMISSION

2276 DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

BY: (DEPUTY ATTORNEY GENERAL)

MAY 2 8 2002
DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

STATE BOARD OF VETERINARY MEDICINE
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5712

DATE OF ADOPTION:

BY: Brian V. Harpster, VMD
BRIAN V. HARPSTER, V.M.D.

TITLE: CHAIRMAN
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

[ ] Check if applicable
Copy not approved.
Objections attached.

Copy below is approved as to form and legality. Executive or Independent Agencies.

4/29/02
DATE OF APPROVAL

(Deputy General Counsel ~~(Chief Counsel, Independent Agency~~
(Strike inapplicable title)

[ ] Check if applicable. No Attorney General approval or objection within 30 day after submission.

NOTICE OF PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF VETERINARY MEDICINE
49 PA. CODE, CHAPTER 31
PROFESSIONAL CONDUCT, PRESCRIPTION DRUGS

The State Board of Veterinary Medicine (Board) proposes to amend 49 Pa. Code § 31.21 (relating to professional conduct) as set forth in Annex A. The proposed regulation would require veterinarians to dispense prescription drugs in child resistant or manufacturer's original packaging; require veterinarians to place certain information on the label of dispensed prescription drugs; require veterinarians to dispense or administer prescription drugs and other medications only if they are within the manufacturer's expiration date; and provide that a veterinarian will not be disciplined for refusing to issue a written prescription, rather than dispensing a prescription drug, if the veterinarian has a good faith belief that a written prescription may be misused.

Effective Date

The rulemaking would be effective upon publication of the final form regulation in the Pennsylvania Bulletin.

Statutory Authority

Section 5(2) of the Veterinary Medicine Practice Act (Act), Act of December 27, 1974, P.L. 995, No. 326, as amended, 63 P.S. § 485.5(2), authorizes the Board to adopt rules and regulations of professional conduct appropriate to establish and maintain a high standard of integrity, skills and practice in the profession of veterinary medicine.

Background and Need for Amendment

The Board currently has no regulations addressing the issues of dispensing, packaging and labeling of drugs by a veterinarian. Several inquiries have been addressed to the Board regarding the proper packaging of veterinary drugs. In the past, it was common for veterinarians to dispense prescription drugs in paper envelopes. However, both professionals and the public have become more aware of the dangers inherent in having prescription drugs in the home.

Current federal regulations require drugs dispensed for human consumption to be packaged in child resistant packaging. Approximately 60% of the drugs used by a small animal veterinary practitioner are also prescribed for humans. In the interest of public safety, the Board believes it is appropriate to address the issue of packaging of prescription drugs dispensed by veterinarians. Requiring child resistant or manufacturer's original packaging, except in limited circumstances, would promote the safety of children who may come into contact with prescription drugs dispensed for animals in their home environments. In addition, public safety demands that a prescription drug be readily identified by its label. In the case of an accidental ingestion, such information may be life saving.

In a disciplinary context, the Board has determined that a veterinarian's use of outdated prescription drugs is a violation of the Veterinary Medicine Practice Act, because such conduct fails to conform to the standards of acceptable and prevailing veterinary medical practice. However, there are no regulations that specifically restrict a veterinarian to dispensing and administering only prescription drugs and other drugs that are not date-expired. Some of the states surrounding Pennsylvania have adopted regulations specifically precluding the use of outdated prescription drugs or drugs. The proposed prohibition on the use of outdated prescription drugs or drugs would be purposefully broader than the packaging and labeling requirements. The packaging and labeling requirements of the proposed rulemaking would apply only to prescription drugs (those determined by the U.S. Food and Drug Administration to be limited to use on the order of a veterinarian or other medical doctor); in contrast, the prohibition on the use of outdated prescription drugs or drugs would apply to all drugs, whether or not a prescription is required for their use.

Finally, there are no current regulations addressing the provision of written prescriptions to clients. Both veterinarians and consumers have questioned the Board about proper veterinary practice related to providing a written prescription for veterinary drugs. The Board therefore proposes this regulation to establish the standard of professional conduct of a veterinarian with regard to written prescriptions.

Description of Proposed Amendments

The Board proposes to amend its professional conduct regulations at 49 Pa. Code § 31.21 to add a new Principle 8 related to prescription drugs and drugs. The proposed regulation would, with just three exceptions, require a veterinarian to dispense prescription drugs in child resistant packaging. The regulation would set forth requirements for the proper labeling of prescription drugs dispensed by a veterinarian. The regulation would mandate that veterinarians dispense or administer only currently dated drugs. Finally, the regulation would provide that a veterinarian will not be disciplined for refusing to issue a written prescription to a client if the veterinarian has a good faith belief that the prescription may be misused.

Definitions

Subsection (a) of the proposed regulation would define "drug" as that term is defined in both Federal and State law, at 21 U.S.C. § 321(g) and 35 P.S. § 780-102. "Prescription drug" would be defined as any drug, except for blood and blood components intended for transfusion, required by Federal law, including Federal regulation, to be dispensed only by a prescription. This definition encompasses both the definition of prescription drug and veterinary prescription drug in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 353(b) and 353(f), and is consistent with the definition of "prescription drug" used in the Code of Federal Regulations, 21 C.F.R. § 203.3(y).

Prescribing Limited to Animals Under the Care of the Veterinarian

Subsection (b) of the proposed regulation would limit veterinarians to prescribing prescription drugs for animals that are under the veterinarian's care. This provision would require that the veterinarian or one of his authorized licensed associates have personal, first hand knowledge of and medical responsibility for the animal for which the drug is prescribed. This provision is designed to ensure the safety of animals and prevent unscrupulous persons from obtaining prescription drugs by misrepresenting information to a veterinarian. As an alternative, a veterinarian may also prescribe prescription drugs for an animal if the veterinarian has made medically appropriate and timely visits to the premises where the animal is kept. This alternative would set forth the appropriate criteria for a veterinarian who works with herd animals.

Packaging Requirements

Subsection (c) of the proposed regulation would require veterinarians to dispense prescription drugs, other than for food animals, in child resistant or manufacturer's original packaging. The draft sent to interested parties used the term "safety closure packaging" instead of "child resistant packaging." Several commentators asked the Board to clarify what was intended by "safety closure" packaging. The Board determined that the standard language in use in federal regulations for the appropriate type of packaging is "child resistant" packaging, and has adopted this term for its regulation. See, e.g., 16 C.F.R. § 1700.15.

The regulation would allow a veterinarian to dispense a prescription drug in the manufacturer's original packaging for several reasons. First, this type of packaging is often inherently child resistant. For example, manufacturers sometimes package pills and single dose topical preparations in a sheet of individually separated, sealed plastic containers. Second, it may be impractical for a veterinarian to repackage certain types of prescription drugs. For example, tubes of an ointment would be impossible to repackage and, depending on the size of the tube, it might be impractical or costly to place the entire tube inside a child resistant package. Finally, some drugs used by veterinarians are dispensed in such quantity that it would be difficult for the veterinarian to obtain safety closure packaging to accommodate the medication. Moreover, this exemption for manufacturer's original packaging would not exempt medications with a high risk of accident, such as syringes pre-filled with the correct dosage of a drug because the syringe does not come pre-filled from the manufacturer. No hardship would be created for the veterinarian, because safety closure packaging for syringes is readily available.

The following two exceptions would be permitted: (1) when dispensing for food animals; and (2) when the client specifically requests alternate packaging. Dispensing for food animals is exempted for three reasons. First, such drugs are not normally kept within the reach of children, thus lessening the danger of accidental ingestion. Second, laypersons administering drugs to food animals

are generally familiar with safe handling procedures because administration of drugs is a common part of animal husbandry. Third, because drugs dispensed for food animals are often dispensed on a "per herd" basis, their quantity would make meeting the general requirement impractical and costly.

Finally, an exemption is permitted pursuant to a client's request to allow a veterinarian to dispense drugs to a person who has difficulty opening child resistant packaging in a container that is more easily opened by that person. This exemption mirrors the exemption to the child resistant packaging requirement for human drugs in federal law. See, 16 C.F.R. § 1701.1(d).

Labeling Requirements

Subsection (d) of the regulation would address labeling requirements for prescription drugs dispensed by veterinarians. Requiring information about the prescribing and/or dispensing veterinarian on the medication's label would serve the public interest by allowing consumers immediate access to veterinarian contact information in the case of questions or concerns about the prescription drug or its effects, and in case of an emergency accidental ingestion. The regulation would require the name, address and telephone number of the prescribing veterinarian and the name and telephone number of the dispensing veterinarian, if different. The address of the dispensing veterinarian, if a different veterinarian than the veterinarian who prescribed the drug, is unnecessary because the client would already know the address of the dispending veterinarian because the client would have to go to the dispensing veterinarian to pick up the medication. The information required would enable the two veterinarians to more easily communicate with each other, and would allow the client ready access to the contact information of the prescribing veterinarian, who is in the best position to answer questions or concerns about the drug prescribed.

The information regarding the name, potency, quantity of the drug, and date dispensed would permit a veterinarian, medical doctor or poison control center to more accurately provide the appropriate treatment in the case of accidental ingestion, and would provide important information to enable a veterinarian to answer a client's questions. Requiring directions for use and cautionary statements would aid the veterinary client in proper administration of the drug. The reference to cautionary statements required by law encompasses federal law that requires the statement that the drug may only be dispensed on the prescription of a veterinarian and any other cautionary statements that federal law may require to be placed on specific drugs. Providing the expiration date of the drug would identify the drug as either within the expiration date, or expired and requiring disposal. Other information required would include the number of refills allowed and the name of the patient, if applicable, that is, when not prescribed for a herd.

Requirement that Veterinarians Administer and Dispense only Currently Dated Medications

Section 21(11) of the Act, 63 P.S. §485.21(11), authorizes the Board to discipline licensees who depart from, or fail to conform to, the standards of acceptable and prevailing veterinary medical practice. The Board's regulations currently do not address the issue of whether a veterinarian departs from the standards of acceptable and prevailing veterinary medical practice by prescribing, administering or dispensing a medication that is expired. The Board has reviewed the issue and found that the acceptable and prevailing standards of veterinary medical practice demand that veterinarians administer or dispense only medications that are within the date set by the manufacturer as the drug's effective date. The determination of this expiration date has been given thorough review by the U.S. Food and Drug Administration and the Board finds that it is the date that shall determine whether a drug is current or expired.

The Board uses the term "drugs" in this section of the proposed regulation, rather than using the term "prescription drugs." The Board intends to require that all drugs administered or dispensed by a licensed veterinarian, whether or not the drug is a prescription drug, must be current, within the date as determined by the manufacturer. The Board believes that the safety and efficacy of outdated drugs, as well as prescription drugs, could negatively impact the health and safety of animals and their human custodians.

Issuance of Written Prescriptions

Finally, the regulation as submitted for pre-draft commentary required a veterinarian to provide the client with a prescription if one was requested, rather than dispensing the medication. A number of commentators who work with farm animals voiced strong objections to the draft language. Because these veterinarians often dispense drugs in large, multiple dose quantities, providing a prescription rather than the drug itself would make it impossible for the veterinarian to have even minimal knowledge or control over the remaining quantity or expiration date of the drug. This could be particularly dangerous to humans when food animals are involved. The Board determined that its regulation should leave the decision of whether to provide a prescription upon request of a client to the professional judgment of the veterinarian. However, the regulation requires that a veterinarian have a good faith reason for refusing a client's request for a prescription. This provision clarifies the Board's position that a veterinarian should not be motivated solely by profit in determining whether to issue a prescription rather than dispense a medication.

Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1 (February 6, 1996), in drafting and promulgating the regulation, the Board sent the text of the proposed regulation to

interested parties, including state and regional veterinary medical associations, associations of animal health technicians, and schools of veterinary medicine. Several persons submitted comments. One commentator suggested that the Board clarify the term "food animal" to specifically include or exclude equines. The Board determined that it would not further define the term because equines are not intended for human food consumption in this country. Another commentator suggested that the regulation provide that "hazardous or potentially toxic medications are recommended to be dispensed in" child resistant packaging. The Board rejected this suggestion for two reasons. First, if the regulation set forth a recommendation rather than a requirement, the regulation would be impossible to enforce. Second, the Board rejected the suggestion that the packaging requirements be limited to hazardous medications because virtually any prescription drug can be hazardous if accidentally ingested. Comments also suggested requiring the veterinarian's telephone number, method of administration, number of refills authorized and the name of the patient on the drug label. The Board adopted all of these suggestions.

Fiscal Impact and Paperwork Requirements

The proposed amendments should have only a minimal financial impact on licensees, who will be required to purchase child resistant packaging for some of the drugs they dispense. The proposed amendments should have no fiscal impact on the Board, the private sector, the general public or any political subdivisions. In addition, the proposed regulation should not create additional paperwork for licensees, the Board, state government or the private sector.

Sunset Date

The Board continuously monitors its regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Pursuant to section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), the Board submitted a copy of this proposed regulation on June 10, 2002, to the Independent Regulatory Review Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC), and the House Professional Licensure Committee (HPLC). In addition to submitting the proposed rulemaking, the Board has provided IRRC, SCP/PLC, and HPLC with a copy of a detailed Regulatory Analysis Form prepared by the Board in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act (71 P.S. § 745.5(g)), if IRRC has objections to any portion of the proposed rulemaking, it will notify the Board within 10 days of the close of the SCP/PLC and HPLC review period. The notification shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of objections by the Board, the General Assembly, and the Governor prior to publication of the regulations.

Public Comment

Interested persons are invited to submit written comments, suggestions, or objections regarding this proposed rulemaking to Robert Kline, State Board of Veterinary Medicine, P.O. Box 2649, Harrisburg, Pennsylvania, 17105-2649, www.dos.state.pa.us, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

Brian V. Harpster, V.M.D.
Chairman

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS
PART I. DEPARTMENT OF STATE
Subpart a. Professional and Occupational Affairs
CHAPTER 31. STATE BOARD OF VETERINARY MEDICINE

§ 31.21 PROFESSIONAL CONDUCT

***

Principle 8. Drugs.

(a) For purposes of Principle 8, "drug" means: (i) substances recognized in the official United States Pharmacopoeia, official National Formulary, or Federal Food and Drug Administration Approved Animal Drug Products, or any supplement to them; and (ii) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, and (iii) substances (other than food) intended to affect the structure or any function of the human body or other animal body; and (iv) substances intended for use as a component of any substance specified in clause (i), (ii), or (iii), but not including devices as that term is defined in 35 P.S. § 780-102. "Prescription drug" means any drug required by Federal law, including Federal regulation, to be dispensed only by a prescription.

(b) A veterinarian shall only prescribe prescription drugs to animals that are under the veterinarian's care. For purposes of this section, "under the veterinarian's care" means that the veterinarian or one of the veterinarian's licensed associates has examined the animal or has made medically appropriate and timely visits to the premises where the animal is kept.

(c) Prescription drugs dispensed by a veterinarian, other than drugs for food animals, shall be dispensed in child resistant packaging or in the manufacturer's original packaging, except when the client specifically requests other packaging.

(d) Prescription drugs dispensed by a veterinarian shall be labeled with, at a minimum, the following information:

(1) The name, address and telephone number of the prescribing veterinarian and the name and telephone number of the dispenser, if different;

(2) The brand or generic name of the drug;

(3) The potency and the quantity of the drug;

(4) The number of refills allowed, if any;

(5) Adequate directions for use, which shall include quantity of dose, frequency of administration or application, duration of administration or application, and route or method of administration or application;

(6) Any cautionary statements specified by the veterinarian or required by Federal law, including, but not limited to, the Federal Food Drug and Cosmetic Act and chapter 21 of the Food and Drug Administration regulations;

(7) The name of the patient, if applicable;

(8) The date the drug was dispensed;

(9) The expiration date of the drug.

(e) Veterinarians shall dispense or administer only drugs, including prescription drugs, that are within the expiration date specified by the manufacturer, and shall dispense or administer only drugs that will not expire within the prescribed treatment period.

(f) Upon request, a veterinarian shall provide a client with a written prescription for an animal that is under the veterinarian's care, except that a veterinarian may refuse to do so without being subject to discipline if the veterinarian has a good faith belief that the prescription may be misused.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF VETERINARY MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7134

June 10, 2002

The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Veterinary Medicine
16A-5712: Prescription Drugs

Dear Chairman McGinley:

Enclosed is a copy of a proposed rulemaking package of the State Board of Veterinary Medicine pertaining to prescription drugs.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Brian V. Harpster, VMD

Brian V. Harpster, V.M.D., Chairperson
State Board of Veterinary Medicine

BVH/TLM:kmh
Enclosure
cc: John T. Henderson, Jr., Chief Counsel
Department of State
David M. Williams, Acting Commissioner
Bureau of Professional and Occupational Affairs
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Herbert Abramson, Senior Counsel in Charge
Department of State
Teresa Lazo-Miller, Counsel
State Board of Veterinary Medicine
State Board of Veterinary Medicine

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5712
SUBJECT:	State Board of Veterinary Medicine - Professional Conduct, Prescription Drugs
AGENCY:	DEPARTMENT OF STATE

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
6-10-02	Lou A. Clark	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
6/10/02	John E Jordan	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICSENSURE
6/10/02	Elina Pazán	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
6/10/02	Maya Cavas	LEGISLATIVE REFERENCE BUREAU

May 30, 2002